

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

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MAYBERRY, JERRY,

Plaintiff,

v.

BRISTOL-MYERS SQUIBB CO., et al.,

Defendants.

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Civil Action No. 07-942 (FLW)

RUTLEDGE, BILLY,

Plaintiff,

v.

BRISTOL-MYERS SQUIBB CO., et al.,

Defendants.

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Civil Action No. 07-1099 (FLW)

**OPINION**

**WOLFSON, District Judge:**

This matter comes before the Court on two separate motions to dismiss pursuant to Rule 12(b)(6) and Rule 9(b) of the Federal Rules of Civil Procedure brought by defendants Bristol Myers-Squibb Company, Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc., (collectively, "Defendants"). Plaintiffs Jerry Mayberry and Billy Rutledge (collectively, "Plaintiffs") bring separate suits against Defendants because they allege that they suffered injuries as a result of Defendants' unlawful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and sale of the

prescription drug Plavix.<sup>1</sup> In that respect, each of Plaintiffs' First Amended Complaint ("Amended Complaint") asserts various Mississippi state and common law claims against Defendants. In the present matter, Defendants move to dismiss Count V, i.e., negligent misrepresentation claim and Count VI, i.e., fraud claim pursuant to the Mississippi Consumer Protection Act, Miss. Code § 75-24-5, et seq., asserted by each of the plaintiffs. For the reasons that follow, Defendants' motions to dismiss these counts are granted.

## BACKGROUND FACTS

### I. Procedural History

Plaintiffs, citizens of Mississippi, filed two separate complaints against Defendants asserting claims under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, et seq., the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, et seq., the New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.9, et seq., the New Jersey Uniform Commercial Code, N.J.S.A. 12A:2-313, and the common law of the State of New Jersey, invoking this Court's diversity jurisdiction. See Plaintiffs' Complaints, ¶¶ 6-8. Plaintiffs are among the individual claimants<sup>2</sup> that lodged separate complaints<sup>3</sup> against Defendants in this district between October 2006 and March 2007, invoking this Court's diversity jurisdiction and asserting similar claims under New Jersey law based upon injuries

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<sup>1</sup> Although Plaintiffs bring separate suits against Defendants, this Opinion addresses Defendants' motion as to both Plaintiffs because Plaintiffs assert identical Mississippi state law claims.

<sup>2</sup> Initially, claims were filed in twenty-four individual cases, however, a Michigan plaintiff in the matter of Felmlee v. Bristol-Myers Squibb Co., No. 06-6240, voluntarily dismissed her claim in February, 2008.

<sup>3</sup> A number of the twenty-three claimants were joined in their actions by spouses asserting claims for loss of consortium.

allegedly suffered as a result of Defendants' alleged negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and/or the sale of Plavix. Id. A brief recitation of the procedural history in the related matters is necessary to a full understanding of the prolonged procedural history in this matter.

In January 2007, prior to the filing of the instant action, Defendants filed motions to dismiss pursuant to Fed.R.Civ.P. 12(b)(6) in the matters of Hall v. Bristol-Myers Squibb, No. 06-CV-5203 (hereinafter, "Hall"), and Skilstaff v. Bristol-Myers Squibb, No. 06-CV-4965 (hereinafter, "Skilstaff")<sup>4</sup>, and indicated their intention to file similar motions in the other Plavix cases pending before this Court. In March 2007, this Court, without objection from the parties, administratively terminated Defendants' motions in Hall and Skilstaff having determined that two cases then pending before the New Jersey Supreme Court addressed the central issues to be decided by this Court on Defendants' motions to dismiss. The parties further agreed that all Plavix cases filed in this district be held in abeyance. Following the issuance of the New Jersey Supreme Court's decisions in Rowe v. Hoffman-LaRoche, 189 N.J. 615 (2007), and International Union of Operating Engineers, Local #68 v. Merck, 192 N.J. 372 (2007), the plaintiff in Skilstaff voluntarily dismissed the action and this Court granted Defendants' request to file a single omnibus motion to dismiss applicable to all personal injury Plavix lawsuits then pending in this district.

One of the main issues to be determined by this Court in the omnibus motion was the federal preemption of the plaintiffs' individual state law claims. In February 2008, however, in light of the

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<sup>4</sup> The plaintiff in the matter of Skilstaff v. Bristol-Myers Squibb, is not among the twenty-three individual claimants seeking damages for personal injuries, rather Skilstaff was an Alabama third-party payor seeking certification of a class of third-party payors for violations of the New Jersey Consumer Fraud Act.

fact that the Third Circuit had pending two separate cases, Colacicco v. Apotex, Inc., and McNellis ex. rel. DeAngelis v. Pfizer, Inc., on its docket regarding substantially similar preemption issues, as did the United States Supreme Court, Levine v. Wyeth, this Court administratively terminated the personal injury Plavix cases pending in this district and permitted plaintiffs to re-file amended complaints in the event there were viable claims after the decisions from the Higher Courts. Following the issuance of the Supreme Court's decision in Levine v. Wyeth, \_\_\_ U.S. \_\_\_, 129 S.Ct. 1187, 173 L.Ed. 2d 51 (2009), this Court reinstated the closed cases and, on May 1, 2009, each of the plaintiffs filed an amended complaint. In the amended complaints, each individual plaintiff brought claims under the laws of the states in which they reside, rather than New Jersey, as originally plead. Thereafter, Defendants moved to dismiss certain counts of the amended complaint filed by each individual plaintiff. It is the Defendants' motions to dismiss Plaintiffs' Counts V and VI that this Court now considers.

## **II. Factual Background**

The following version of events assumes Plaintiffs' allegations in their Amended Complaint to be true because Defendants move pursuant to Fed. Civ. R. P. 12(b)(6). The Court will recount only those facts relevant to the present matter.

Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc. (collectively, the "Sanofi Defendants") partnered with Bristol-Myers Squibb Company ("BMS") to manufacture and market Plavix in the United States. See Amended Complaint ("Am. Compl."), ¶¶ 2-5.<sup>5</sup> In April 1997, the Sanofi Defendants and BMS applied for a rare, priority regulatory review

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<sup>5</sup> Because both Plaintiffs' Amended Complaints are substantially identical, the Court will refer to them collectively, unless otherwise noted.

by the Food and Drug Administration (“FDA”) clearing the way for Defendants to bring Plavix to market in November 1997. Id., ¶ 11. According to Plaintiff, Defendants heavily marketed Plavix directly to consumers through television, magazine, and internet advertising, falsely touting Plavix “as a ‘super-aspirin’ that would give a person even greater cardiovascular benefits than a much less expensive, daily aspirin, while being safer and easier on a person’s stomach than aspirin.” Id., ¶ 13. Plaintiffs allege that Defendants either knew or should have known, based upon their own studies, that not only was Plavix not more efficacious than aspirin in terms of preventing heart attacks and strokes, the risk of suffering a heart attack, stroke, internal bleeding, blood disorder or death far outweighed any benefit from the drug. Id., ¶ 14.

As evidence that Defendants were indeed aware of their false and misleading promotion of Plavix, Plaintiffs point to a November 1998 letter from the FDA wherein the FDA instructed Defendants to cease promoting Plavix for off-label use in patients undergoing coronary artery stent placement.<sup>6</sup> Id., ¶ 18. Plaintiffs also point to the same FDA reprimand wherein Defendants were instructed to cease promoting Plavix at an off-label dose, which was nearly four (4) times that of the recommended dosage. Id. In addition to criticizing Defendants for promoting Plavix for unapproved use, the FDA also criticized Defendants for overstating the safety profile of Plavix with respect to its use with other drugs. Id., ¶ 19. In particular, Plaintiffs point to the fact that Defendants touted the safety of Plavix when combined with aspirin (known as “dual therapy”) when, in fact, its safety had not been established. Id. According to Plaintiffs, Defendants’ claim regarding the safety of dual therapy has now been proven to be untrue in a recent study published in the New England Journal

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<sup>6</sup> As discussed more fully *infra*, the Court will consider the extrinsic documents referenced in the FAC as they were explicitly relied upon by Plaintiff in the FAC.

of Medicine in April 2006 entitled Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance (the “CHARISMA Study”<sup>7</sup>). Id.

As further evidence of Defendants’ allegedly false and misleading promotional practices, Plaintiffs point to a December 1998 letter from the FDA, wherein the FDA demanded that Defendants cease the distribution of advertising materials that claimed that Plavix has been proven to be more effective than aspirin. Id., ¶ 20. The FDA criticized Defendants’ materials as an overstatement of efficacy, which was unsubstantiated and lacking in fair balance. Id. Again in 2001, the FDA ordered Defendants to immediately cease distribution of promotional material that made false or misleading claims about Plavix. Id., ¶ 21. Specifically, the FDA noted that the clinical evidence of the efficacy of Plavix is derived from Defendants’ study entitled Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events Trial (the “CAPRIE” Study). Id. Defendants’ promotional material depicted a 19.2% relative risk reduction for Plavix versus aspirin, yet the actual findings of the CAPRIE Study were that Plavix was not proven to be significantly more effective than aspirin. Id. Additionally, the FDA again instructed Defendants to cease claiming that the use of Plavix combined with aspirin was safe and effective. Id.

According to Plaintiffs, in addition to misinforming physicians and consumers through false and misleading promotional materials and advertising, Defendants’ drug representatives also misinformed physicians regarding the proper types of patients who should be prescribed Plavix, the duration of its proper usage and the applications for which Plavix is safe and FDA approved. Id., ¶ 22. Specifically, Plaintiffs point to the fact that the drug representatives have encouraged

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<sup>7</sup> The CHARISMA Study derives its name from the Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance trial, which was the subject of the article.

physicians to prescribe Plavix to a broad population who would receive the same therapeutic benefit from aspirin alone, without the purported risk of death, and to use Plavix for unapproved applications. Id., ¶ 23.

Plaintiffs allege that after a nearly eight-year run of misleading physicians and the public regarding the safety and efficacy of Plavix, scientific studies now reveal that Plavix is in fact dangerous. Id., ¶ 25. Citing a study published in The New England Journal of Medicine in January 2005, entitled Clopidogrel versus Aspirin and Esomeprazole to Prevent Recurrent Ulcer Bleeding (the “Chan Study”), Plaintiff notes the dangers of Plavix. Specifically, Plaintiffs contend that the Chan Study demonstrates the fallacy of Defendants’ assertions that Plavix is safer and more effective for patients suffering from gastrointestinal intolerance to aspirin. Id., ¶ 26. Plaintiffs point out that the Chan Study recommended that prescribing guidelines for Plavix be changed so that patients would not erroneously believe that Plavix is safer on the stomach than aspirin, in light of the Study’s findings that recurring stomach bleeding was 8.6% in the Plavix group versus only .7% in the aspirin group. Id. Plaintiffs additionally cite to the Chan Study’s finding that an aspirin a day plus esomeprazole (the generic name for an inexpensive over-the-counter proton pump inhibitor such as Prilosec) is far more cost effective than paying for the four-dollar per day Plavix pill, which greatly increases the risk of stomach bleeding. Id., ¶27. Finally, citing the CHARISMA Study, Plaintiffs contend that Plavix plus aspirin (“dual therapy”) is only minimally more effective than aspirin plus placebo at preventing atherothrombotic events, and more significantly, does more harm than good in those patients without peripheral arterial disease or acute coronary syndrome in that it poses a 20% increased risk to the patient of suffering bleeding injuries, heart attacks, stroke and death. Id., ¶ 28.

Due to these alleged illegal practices, each Plaintiff asserts, inter alia, a fraud claim pursuant

to the Mississippi Consumer Protection Act, Miss. Code § 75-24-5, et seq. (“MCPA” the “Act”), and a Mississippi state common law claim of negligent misrepresentation; these claims are the subject of this motion. In connection with these two claims, Plaintiff Mayberry alleges that he “was prescribed Plavix, to be taken in combination with aspirin (known as “dual therapy”) on or around June 10, 2004 in connection with his peripheral vascular disease and atherosclerotic heart disease.” Plaintiff Mayberry further alleges that in November 2004, “he was told he was chronically anemic.” Thereafter, “on or around March, April, and May 2005, he went to the hospital and was told he had upper intestinal bleeding and given transfusions of blood, up to four units at a time.” See Mayberry Amended Complaint, ¶ 30 (hereinafter referred to as “Mayberry Compl.”).

In a similar fashion, Plaintiff Rutledge alleges that he “was prescribed Plavix, to be taken in combination with aspirin . . . on or around April 2004 in connection with stent placement. On December 6, 2005 he collapsed and was brought to the hospital.” Plaintiff Rutledge further alleges that he “was found to have acute gastrointestinal bleeding and was given a transfusion,” and was given several blood transfusions after being found to be anemic. See Rutledge Amended Complaint, ¶ 30 (hereinafter referred to as “Rutledge Compl.”).

As result of the alleged injuries, Plaintiffs, in Count VI of their respective Amended Complaints, allege that Defendants violated the MCPA by making “untrue, deceptive, and/or misleading representations of material facts, and omitted and/or concealed material facts from the public, including the Plaintiff[s], concerning the use and safety of Plavix.” Mayberry Compl., ¶ 90; Rutledge Compl., ¶ 91. In that connection, Plaintiffs allege that “Defendants knew and should have known, that Plavix was unreasonably dangerous and defective, and had a propensity to cause serious and potentially life threatening side effects.” Mayberry Compl., ¶ 88; Rutledge Compl., ¶ 89.



Specifically, Plaintiffs allege that “Defendant’s practice of promoting Plavix placed and continues to place all consumers of Plavix at risk of serious injury and potentially lethal side effects.” Mayberry Compl., ¶ 92; Rutledge Compl., ¶ 93. Plaintiffs further allege that “Defendants’ statements and omissions were made with the intent that the Plaintiff[s], and Plaintiff[s’] prescribing physician, would rely on them.” Mayberry Compl., ¶ 93; Rutledge Compl., ¶ 94. As a result of the alleged illegal practices, Plaintiffs claim that they have “suffered severe and permanent physical injuries.” Mayberry Compl., ¶ 97; Rutledge Compl., ¶ 98.

Similarly, Count V alleges that “Defendants falsely represented to Plaintiff[s] in direct to consumer advertising and indirectly through misrepresentations to the prescribing physician, that Plavix was safe and effective. The representations by Defendants were in fact false and Plavix was not safe and was in fact dangerous to Plaintiff[s’] health.” Mayberry Compl., ¶ 73; Rutledge Compl., ¶ 74. Each Plaintiff claims that “[a]t the time the representations were made, Defendants concealed from Plaintiff[s] and Plaintiff[s’] prescribing physician[s] information about the propensity of Plavix to cause great harm.” Mayberry Compl., ¶ 74; Rutledge Compl., ¶ 75. In that regard, Plaintiffs allege that “Defendants’ misrepresentations were made by Defendants with the intent to induce Plaintiff[s] to use Plavix, to Plaintiff[s’] detriment.” Mayberry Compl., ¶ 76; Rutledge Compl., ¶ 77. Plaintiffs further allege that “Plaintiff[s] and Plaintiff[s’] healthcare provider[s] justifiably relied on Defendants’ misrepresentations and consequently, Plaintiff[s’] ingestion of Plavix was to Plaintiff[s’] detriment.” Mayberry Compl., ¶ 80; Rutledge Compl., ¶ 81.

Now, Defendants move to dismiss Count V, the negligent misrepresentation claim, and Count VI, the MCPA claim, of both of Plaintiffs’ Amended Complaints. The Court will turn to address the sufficiency of these claims.

## DISCUSSION

### I. Standard of Review

When reviewing a motion to dismiss on the pleadings, courts "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008) (citation and quotations omitted). In Bell Atlantic Corporation v. Twombly, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), the Supreme Court clarified the 12(b)(6) standard. Specifically, the Court "retired" the language contained in Conley v. Gibson, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Id. at 561 (quoting Conley, 355 U.S. at 45-46). Instead, the factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." Id. at 555. As the Third Circuit has stated, "[t]he Supreme Court's Twombly formulation of the pleading standard can be summed up thus: 'stating ... a claim requires a complaint with enough factual matter (taken as true) to suggest' the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element.'" Phillips, 515 F.3d at 234 (quoting Twombly, 127 S.Ct. at 1965).

In affirming that Twombly standards apply to all motions to dismiss, the Supreme Court recently explained the principles. "First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." Ashcroft v. Iqbal, 129 S.

Ct. 1937, 1949 (2009); Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009).<sup>8</sup> “Second, only a complaint that states a plausible claim for relief survives a motion to dismiss.” Id. at 1950. Therefore, “a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth.” Id. Ultimately, “a complaint must do more than allege the plaintiff’s entitlement to relief. A complaint has to ‘show’ such an entitlement with its facts.” Fowler, 578 F.3d at 211.

Before reaching the merits of Plaintiffs’ claims, there is a threshold procedural question as to the documents and exhibits this Court may consider on this motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6). As previously referenced in this Court’s discussion of the Factual Background, Plaintiffs supply this Court with several exhibits, including: (1) a December 1998 FDA letter addressed to Sanofi Pharmaceuticals, Inc.; (2) a copy of the CHARISMA Study; (3) a November 1998 FDA letter addressed to Sanofi Pharmaceuticals, Inc.; (4) a May 2001 FDA letter addressed to Sanofi-Synthelabo Inc.; (5) the Chan Study; and (6) a Mediation Letter dated March 12, 2009. Additionally, Defendants provide the Court with the November 17, 1997 approval letter for Plavix. While generally a court may not consider matters outside the pleadings when ruling on a motion to dismiss, documents that are “integral to or explicitly relied upon in the complaint” may indeed be considered without converting a motion to dismiss into a motion for summary judgment. In re Rockefeller Ctr. Props., Inc. Sec. Litig., 184 F.3d 280, 287 (3d Cir.1999) (emphasis and citations omitted). Accordingly, the referenced exhibits are properly before the Court on the instant motion

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<sup>8</sup> The Court notes that because the briefing in this matter was filed shortly after the United States Supreme Court’s decision in Ashcroft, counsel for Defendants moved for leave to file supplemental briefing addressing the standard of review applicable to the instant motion. This Court found additional briefing unnecessary and, accordingly, denied Defendants’ request.

to dismiss.

## **II. The MCPA Claim**

### **A. Alternative Dispute Resolution**

At the outset, Defendants submit that Plaintiffs' MCPA claims should be dismissed for their failure to attempt to resolve this claim through informal dispute resolution prior to commencing suit as required by Miss. Code § 75-24-15. Pursuant to subsection (2) of Section 15, "[i]n any private action brought under this chapter, the plaintiff must have first made a reasonable attempt to resolve any claim through an informal dispute settlement program approved by the Attorney General." Miss. Code § 75-24-15(2). Compliance with this requirement is mandatory. See Cole v. Chevron USA, Inc., 554 F. Supp. 2d 655, 667-68 (S.D. Miss. 2007). Indeed, the Court of Appeals of Mississippi dismissed a private action against an insurance provider for alleged violations of the MCPA based upon a failure to comply with this alternative dispute mechanism. See Taylor v. Southern Farm Bureau Cas.f Co., 954 So. 2d 1045, 1049 (Miss. App. 2007). The Taylor court noted that the plaintiff's failure to allege any attempt to satisfy the informal dispute settlement requirement of Section 75-24-15(2) was grounds for affirming dismissal of the MCPA claim for failure to state a claim. Id. Additionally, the United States District Court for the District of Massachusetts refused to include Mississippi consumers alleging violations of the MCPA in a putative nationwide consumer class action for, inter alia, failure to allege compliance with Section 75-24-15(2). In re Pharmaceutical Industry Average Wholesale Price Litigation, 230 F.R.D. 61, 84-85 (D. Mass. 2005); see also Cole, 554 F. Supp. 2d at 668.

Here, neither Amended Complaint alleges any attempt by Plaintiffs to resolve their respective MCPA claims through a program under the auspices of the Attorney General's office prior to filing

suit. To excuse this deficiency, Plaintiffs argue that they attempted to amicably resolve their MCPA claims before filing their Amended Complaint by way of a letter dated March 12, 2009, wherein Plaintiffs sought to mediate the matter. Plaintiffs also advance that Defendants have had ample notice of their claim, and therefore, should not be able to hide behind this mandatory provision of the MCPA. Plaintiffs' position lacks merit.

Implicit in Plaintiffs' position is their concession that they did not attempt to resolve their MCPA claim through an informal dispute settlement program approved by Mississippi's Attorney General before filing their Amended Complaints. Rather, Plaintiffs point to a mediation letter that clearly does not conform to the MCPA requirement because it was not an approved program by the Attorney General. Indeed, the letter does not even mention these two Plaintiffs or the statutory requirements of the MCPA. Furthermore, whether Defendants were on notice of the claims asserted by Plaintiffs is irrelevant to Plaintiffs' obligations to comply with the prerequisite for maintaining a private right of action under the MCPA. The burden falls on Plaintiffs to attempt to resolve the matter through a program approved by the Attorney General; however, Plaintiffs failed to do so, and therefore, their MCPA claim is dismissed for this reason. See Cole, 554 F.Supp. 2d at 668.

#### **B. Sufficiency of the Pleadings**

Both Plaintiffs' MCPA claims are also dismissed for the additional reason that they fail to state a claim. To state a claim under the MCPA, neither party disputes that Plaintiffs must plead with particularity pursuant to Rule 9(b). In Frederico v. Home Depot, 507 F.3d 188 (3d Cir. 2007), the Third Circuit elucidated the heightened pleading standard under Rule 9(b):

Pursuant to Rule 9(b), a plaintiff alleging fraud must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the "precise misconduct with which [it is] charged." To satisfy this standard, the

plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation.

Id. at 200 (internal citations omitted); In re Supreme Specialties, Inc. Sec. Litig., 438 F.3d 256, 276-77 (3d Cir. 2006)(the Third Circuit advised that pursuant to Rule 9(b), at a minimum, a plaintiff must support his/her allegations of fraud with all the essential factual background that would accompany “‘the first paragraph of any newspaper story’ – that is, the ‘who what, when, where and how’ of the events at issue”(citations omitted)). Moreover, a complaint must do more than assert generalized facts, it must allege facts specific to the plaintiff. Rolo v. City Investing Co. Liquidating Trust, 155 F.3d 644, 658-59 (3d Cir. 1998)(where the complaint failed to allege “what actually happened to either” of the plaintiffs, the complaint did not plead “fraud with the specificity required by Rule 9(b)”). This type of heightened pleading requirement is in accord with the Fifth Circuit precedent. See Tel-Phonic Servs., Inc., v. TBS Int’l, Inc., 975 F.2d 1134, 1139 (5<sup>th</sup> Cir. 1992)(“[a]t a minimum, Rule 9(b) requires particulars of time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby”); Benchmark Elecs., Inc. v. J.M. Huber Corp., 343 F.3d 719, 724 (5<sup>th</sup> Cir. 2003)( “[p]ut simply, Rule 9(b) requires ‘the who, what, when, where, and how’ to be laid out” (citations omitted)).

In their Amended Complaints, Plaintiffs allege a unified course of fraudulent conduct and they rely entirely on that as the basis of their MCPA claims. More specifically, as noted above, Plaintiffs allege that Defendants “knew or should have known, that Plavix was unreasonably dangerous or defective, and had a propensity to cause serious potentially life threatening side

effects.”<sup>9</sup> Plaintiffs further allege that “[d]espite their knowledge, the Defendants omitted material facts in the disclosures they made to the public, the medical community and consumers, including the Plaintiff[s], concerning the safety of Plavix.” As a result, Plaintiffs allege that Defendants violated the MCPA “in that they made untrue, deceptive, and/or misleading representations of material facts, and omitted and/or concealed material facts from the public, including the Plaintiff[s], concerning the use and safety of Plavix.” Plaintiffs’ allegations fall short of complying with Rule 9(b).

Arguing the contrary, Plaintiffs affirm that the Amended Complaint asserts sufficient facts to satisfy Rule 9(b). In particular, Plaintiffs point to ¶¶ 18-29 of the Amended Complaint to support their assertion that they have pled the so-called “newspaper requirements” of Rule 9(b). Summarizing their points, Plaintiffs state (1) that they have alleged who made the misleading statements - Defendants; (2) that they have alleged what was misleading about Defendants’ statements - Defendants advertised Plavix as safe and effective in “dual therapy” treatments, off-label use, and more effective than aspirin; (3) that they have alleged that Defendants’ statements were known to be misleading or should have been known when made - multiple FDA warnings against deceptive advertising of Plavix’s safety and use in certain treatments, as well as scientific studies, both internal and external, refuting Defendants’ wrongful advertising of Plavix; (4) that they have alleged what Defendants’ misrepresentations were - the safety and effectiveness of Plavix as advertised in the face of both FDA warnings to the contrary and numerous scientific studies; and (5) that they have alleged why Defendants’ misrepresentations were misleading - concealment of the

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<sup>9</sup> Since the Court is restating these allegations that were previously set forth in this Opinion, the Court will not repeat the citations to the record here.

risks associated with the use of Plavix, promotion of the safe and beneficial use of Plavix for off-label use in patients receiving arterial stents, even though the FDA and scientific studies warned against such use. Nevertheless, Plaintiffs also suggest that under the circumstances of this case, because information regarding their allegations of fraud are within Defendants' control, less specificity of pleading is required pending discovery.

While Plaintiffs made exhaustive allegations regarding Defendants' alleged illegal practices by relying on FDA correspondence and scientific studies, both Amended Complaints fail to allege with specificity the connection between Defendants' conduct and Plaintiffs' resultant injury. Plaintiffs' only allegations particular to their circumstances that support their MCPA fraud claims can be found in ¶ 30 of the Amended Complaints, wherein Plaintiffs set forth when they were prescribed Plavix and the health issues as a result of taking Plavix. These allegations are insufficient to meet the rigors of Rule 9(b).

Plaintiffs fail to identify any specific advertisements they viewed, how they were misled by these advertisements, how these advertisements affected their prescriptions for Plavix and how these advertisements caused any of their injuries. In other words, both of the Amended Complaints fail to identify which, if any, of the promotional or marketing materials were received, viewed or relied upon by Plaintiffs, and if they were, when these materials were viewed and how they were relied upon. More simply stated, Plaintiffs have failed to allege any specific facts establishing a connection between the alleged conduct of Defendants and the alleged injury claimed. See Kriteley v. Wadekar, No. 05-5383, 2006 U.S. Dist. LEXIS 60309, at \*9-10 (D.N.J. Aug. 25, 2006) ("Plaintiffs offer only general, conclusory statements that Plaintiffs purchased pharmaceutical products manufactured by the company that Defendants were officers and directors of, and that Defendants marketed the



products using false representations, with fraudulent scienter.” Plaintiffs do not allege with particularity any of the facts that would be expected to be within their knowledge: exactly who bought exactly what product when, relying on what false representations made when by whom”); Guilbealt v. R.J. Reynolds Tobacco Co., 84 F.Supp. 2d 263, 269 (D.R.I. 2000)(when a plaintiff claims that a product advertisement or promotion led to injuries, he or she must “identify specific advertising he [or she has] seen and how it ha[s] affected” him or her to comply with Rule 9(b)’s requirements).

Likewise, Plaintiffs fail to allege that their physicians personally received a misrepresentation of fact from Defendants and relied upon that misrepresentation in deciding to prescribe Plavix to their respective plaintiff patients.<sup>10</sup> Rather, Plaintiffs allege only generally that Defendants “omitted material facts in the disclosures they made to the public, the medical community and to consumers, including the Plaintiff[s], concerning the use and safety of Plavix,” and these “statements and omissions were made with the intent that the Plaintiff[s], and Plaintiff[s’] prescribing physician[s], would rely on them.” Although the Amended Complaints also allege that Defendants’ drug representatives have misinformed physicians about the proper types of patients who should be given Plavix, the duration of its proper usage, and the applications for which it is safe and FDA approved, Plaintiffs have not identified the representatives, what was said, when it was said, to whom it was said and how these statements relate to Plaintiffs’ prescriptions of Plavix.

Moreover, these factual allegations are not the type of facts that are within the control of, and therefore subject to concealment by Defendants. Instead, these important details regarding

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<sup>10</sup> Plaintiffs’ Amended Complaints do not provide the names of their prescribing physicians.

misrepresentations made to, and relied upon by, Plaintiffs and their physicians are within Plaintiffs' ken, but are nowhere to be found within their respective Amended Complaint.<sup>11</sup>

The deficiencies of Plaintiffs' Amended Complaints in this context were recently discussed by the court in In re Schering-Plough Corp. Intron/Temodar Consumer Class Action, No. 06-5774, 2009 U.S. Dist. LEXIS 58900 (D.N.J. Jul. 10, 2009) (Chesler, J.) In that case, plaintiffs filed a class action complaint alleging, inter alia, that defendants "engaged in improper and illegal off-label promotion of Intron-A, PEG-Intron, Rebetol and Temodar." Id. at \*6. Plaintiffs further alleged that defendants "orchestrated a campaign to illegally market and promote the Subject Drugs for off label uses . . . and, as a result, Plaintiffs paid for drugs at an inflated price or for drugs that they would not have purchased but for the illicit marketing scheme." Id. at \*7. Similar to Defendants' response here, the defendants there filed a motion to dismiss, among other claims, plaintiffs' fraud and negligent misrepresentation claims.

In dismissing these two specific claims, the court, in a well-reasoned opinion, found that plaintiffs made "sweeping allegations" regarding defendants' alleged promotion, yet they did not plead a single instance in which they, themselves, or any of their prescribing doctors received a

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<sup>11</sup>Indeed, in that connection, each Plaintiff is uniquely equipped to determine from their physician whether the physician received such promotional literature. Even where factual information may be within the domain or control of Defendants, such as the identities of the doctors who received promotional information, Plaintiffs must still "accompany their legal theory with factual allegations that make their theoretically viable claim plausible." In re Burlington Coat Factory, 114 F.3d 1410, 1418 (3d Cir. 1997). Moreover, to "avoid dismissal," a complaint must also delineate at least the nature and the scope of a plaintiff's efforts to obtain, before filing the complaint, the information needed to plead with particularity. Shapiro v. UJB Financial Corp., 964 F.2d 272, 285 (3d Cir. 1992). Plaintiffs have failed to comply with these requirements. Indeed, Plaintiffs' Amended Complaints contain no allegations that the information required for Plaintiffs to meet the Rule 9(b) obligation is solely within Defendants' control.

misrepresentation of fact on which they relied upon in either taking or prescribing any of the subject drugs. Id. at \*117. In addition, the court explained that plaintiffs' common law fraud and negligent misrepresentation claims also failed to state a claim because plaintiffs did not allege a causal connection between their injury and defendants' conduct. Id. at \*119. While In re Schering-Plough dealt with New Jersey's common law claims, the same reasoning applies here since the fraud theory of that case parallels the instant actions. See Suarez v. Playtex Products, Inc., No. 08-2703, 2009 U.S. Dist. LEXIS 63774, at \*8-10 (N.D. Ill. Jul. 24, 2009)(plaintiffs failed to allege with specificity "whether or when they relied on, or even saw, these [misrepresentations] prior to purchasing the coolers"). Accordingly, Plaintiffs fail to inject precision and some measure of substantiation to support their MCPA claim, and therefore, they are dismissed.

### **III. Negligent Misrepresentation**

As a preliminary matter, Plaintiffs dispute that in Mississippi, negligent misrepresentation claims are not fraud in nature, and thus, they need not plead this claim with particularity. For support, Plaintiffs primarily rely on American Realty, Trust, Inc. v. Hamilton Lane Advisor, 115 Fed. Appx. 662 (5<sup>th</sup> Cir. 2004), for the proposition that Rule 9(b)'s stringent pleading requirements do not extend to negligent misrepresentation. But see Benchmark Electronics, Inc. v. J.M. Huber, 343 F.3d 719, 723 (5<sup>th</sup> Cir. 2003)(Rule 9(b) by its terms does not apply to negligent misrepresentation claims and will not apply when parties have separated the negligent misrepresentation claims). In response, relying on American Realty Trust, Inc. v. Travelers Casualty & Surety Co. of Am., 362 F.Supp. 2d 744 (N.D. Tex. 2005), Defendants posit that because Plaintiffs' negligent misrepresentation claims are based on fraudulent conduct, Rule 9(b) should apply. Upon reviewing the cases relied upon by the parties, the Court finds the parties' arguments unavailing because all three cases, Travelers

Casualty, Hamilton Lane and Benchmark Electronics, involved common law negligent misrepresentation claims in Texas, not Mississippi; as such, the reasoning behind these courts' holdings has no applicability in this case.

It appears that Mississippi courts have not addressed whether Rule 9(b) applies to negligent misrepresentation claims. However, the Supreme Court of Mississippi has made clear that "[t]he basis for damages from negligent misrepresentation is the lack of care; the basis for damages resulting from fraud is the want of honesty." Stonecipher v. Kornhaus, 623 So. 2d 955, 964 (Miss. 1993) (quoting First Money, Inc. v. Frisby, 369 So. 2d 746, 750 (Miss. 1979)); see also Fletcher v. Lyles, 999 So. 2d 1271, 1278 (Miss. 2009). "The lack of care in misrepresentation and the want of honesty in fraudulent misrepresentation in business transactions give rise to distinct causes of action, the one in tort, the other in fraud." First Money, 369 So. 2d at 750. While it appears the requirements of Rule 9(b) may not apply to negligent misrepresentation claims in Mississippi because the claim sounds in tort, the Court need not reach this issue in this motion since Plaintiff has failed to plead this Count sufficiently even under the notice pleading standard of Rule 8(a).

To establish a claim for negligent misrepresentation, a plaintiff must establish the following elements: (1) a misrepresentation or omission of a fact; (2) that the representation or omission is material or significant; (3) that the defendant failed to exercise that degree of diligence and expertise the public is entitled to expect of it; (4) that the plaintiff reasonably relied on the defendant's representations; and (5) that the plaintiff suffered damages as a direct and proximate result of his reasonable reliance. Skrmetta v. Bayview Yacht Club, Inc., 806 So. 2d 1120, 1124 (Miss. 2002); Waters v. Allegue, 980 So. 2d 314, 318 (Miss. 2008).

Here, in order to support their negligent misrepresentation claims, Plaintiffs allege that

“Defendants falsely represented to Plaintiff[s] in direct to consumer advertising and indirectly through misrepresentation to the prescribing physician, that Plavix was safe and effective. The representations by Defendants were in fact false and Plavix was not safe and was in fact dangerous to Plaintiff’s health.” Each Plaintiff further alleges that “[a]t the time the representations were made, Defendants concealed from Plaintiff[s] and [their] prescribing physician[s] information about the propensity of Plavix to cause great harm. Defendants negligently misrepresented claims regarding the safety and efficacy of Plavix despite the lack of information regarding the same.”

Viewing these allegations, Plaintiffs fail to state a claim for negligent misrepresentation. While Plaintiffs may have arguably alleged sufficiently elements one, two, three and five, Plaintiffs fail to allege sufficient facts with respect to the fourth element of the claim - that the plaintiff reasonably relied upon the representation or omission. In fact, to allege reliance, Plaintiffs simply provide a threadbare recital of this element. Specifically, Plaintiffs only allege that “Defendants’ misrepresentations were made to Plaintiff[s], as well as the general public. Plaintiff[s] and Plaintiff[s’] healthcare provider[s] justifiably relied on Defendants’ misrepresentations and consequently, Plaintiff[s’] ingestion of Plavix was to Plaintiff[s’] detriment.” *Id.*, ¶ 80. Such allegation is clearly insufficient under the standard set forth in *Iqbal*. Indeed, both of the Amended Complaints lack any allegations regarding which misrepresentations were made to Plaintiffs or their prescribing physicians, and what misrepresentations Plaintiffs relied upon in connection with their decision(s) to take the prescription drug Plavix. Without this information, Plaintiffs’ allegations regarding reliance simply amounts to a mere legal conclusion that does not state a plausible claim which relief can be granted. *See Iqbal*, 129 S. Ct. at 1949. Accordingly, Plaintiffs’ Negligent Misrepresentation claims are dismissed without prejudice.

### CONCLUSION

Based upon the foregoing reasons, Defendants' motions to dismiss Counts V and VI of both Plaintiffs' Amended Complaints are granted. However, with respect to only Count V – the Negligent Misrepresentation claim – Plaintiffs shall have leave to file separate motions to amend the Amended Complaint if they seek to assert such a claim, but they must cure the deficiencies as outlined by the Court. As a final note, should Plaintiffs move to re-plead this claim, it must be clearly averred that the claim is premised upon a theory of negligence.

DATE: December 30, 2009

/s/ Freda L. Wolfson  
The Honorable Freda L. Wolfson  
United States District Judge